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| 10/518,549 | 01/03/2005 | Yukako Fujiwara | 263756US0PCT | 6834 |
| 22850 | 7590 | 11/26/2008 | EXAMINER | |
| OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C. | | | HOLLOWMAN, NANNETTE | |
| 1940 DUKE STREET | | | ART UNIT | PAPER NUMBER |
| ALEXANDRIA, VA 22314 | | | 1612 | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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|------------------------------|--------------------------------------|---|
| Office Action Summary | Application No. 10/518,549 | Applicant(s) FUJIWARA, YUKAKO |
| | Examiner NANNETTE HOLLOWAN | Art Unit 1612 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 09 July 2008.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 17-36 is/are pending in the application.

4a) Of the above claim(s) 22,23,29-31 and 36 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 17-21,24-28 and 32-35 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO/SB/06)
Paper No(s)/Mail Date _____

4) Interview Summary (PTO-413)
Paper No(s)/Mail Date _____

5) Notice of Informal Patent Application

6) Other: _____

DETAILED ACTION

This Office Action is in response to the Amendment filed July 9, 2008. All previous rejections have been withdrawn unless stated below.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Response to Election/Restrictions

Applicant's election without traverse of:

(A) sucrose monostearate for the sucrose fatty acid ester;
(B) ceramide 2 for the sphingosine or a derivative thereof;
(C) water for the aqueous component;
(D) isostearic acid for the branched fatty acid having a melting point of 80°C or less;

(E) the optional sterol is absent; and
(F) the optional drug is absent

in the reply filed on July 9, 2008 is acknowledged.

Claims 22-23, 29-31 and 36 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species and invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on July 9, 2008.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 17-21, 24-28 and 32-35 are rejected under 35 U.S.C. 102(e) as being anticipated by Naru et al (US Patent Publication US 2004/0033246).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Naru et al. disclose a cosmetic composition comprising (A) sucrose fatty acid ester (p. 3, paragraph [0037]); (B) ceramide II (p. 2, paragraph [0027]); (C) water (p. 6, example 5); and (D) isostearic acid ((p.3, paragraph, [0036]). Naru et al. disclose the percents as disclosed are by weight (p. 1, paragraph [0014]). Naru et al. disclose component (A) in example 5 and 6 at 0.5% by weight, component (B) in a range of 0.001-10% by weight (p.2, paragraph [0033]), component (C) in example 5 at 66% by

weight, and component (D) as an oily agent in example 8 at 5% by weight (claims 32).

Naru et al. further disclose the composition may be used as a dispersed liquid and is considered to meet the limitation of instant claim 35 (p. 3, paragraph [0041]).

Claim Rejections - 35 USC § 103 (new rejection)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This rejection would not be overcome by the declaration, as it does not distinguish the instant claims from the prior art or show unexpected results in view of the instantly applied art. The above reference is being understood to anticipate the claims while not explicitly disclosing a vesicle, but for *arguendo* the following obviousness rejection is included.

Claims 17-21, 24-28 and 32-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Naru et al (US Patent Publication US 2004/0033246), and further in view of Tsuchida et al. (EP 1340494 A1)

Naru et al. disclose a cosmetic composition comprising (A) sucrose fatty acid ester (p. 3, paragraph [0037]); (B) ceramide II (p. 2, paragraph [0027]); (C) water (p. 6, example 5); and (D) isostearic acid ((p.3, paragraph, [0036])). Naru et al. disclose the percents as disclosed are by weight (p. 1, paragraph [0014]). Naru et al. disclose component (A) in example 5 and 6 at 0.5% by weight, component (B) in a range of 0.001-10% by weight (p.2, paragraph [0033]), component (C) in example 5 at 66% by weight, and component (D) as an oily agent in example 8 at 5% by weight (claims 32). Naru et al. further disclose the composition may be used as a dispersed liquid and is considered to meet the limitation of instant claim 35 (p. 3, paragraph [0041]). Naru et al. teaches a composition made with mainly the same components and the methods are significantly the same; therefore, should form a composition that substantially has the same characteristics, i.e. vesicle dispersion.

Naru et al. do not specifically disclose the dispersions are vesicle dispersions.

Tsuchida et al. (EP 1340494 A1) disclose vesicle dispersions with shortened preparation time and increased yields, which enable the controlling of particle size without the use of organic solvents or surfactant, and enable the mass production of safe vesicle dispersions useful in the cosmetic field (p. 2, paragraph [0001]). Tsuchida et al. disclose the particles sizes of the vesicles are made to be about 1.3 to 4 times that of the desired vesicle product (p. 4, paragraph [0025]). Tsuchida et al. further disclose

a vesicle of 0.5 to 300 μ m, which can be extruded through a filter of desired pore size and is understood to meet the limitation of instant claim 34 (p. 4-5, paragraph [0026]).

It would have been obvious to one of ordinary skill in the art to use the dispersed liquid composition of Naru et al. as vesicle dispersions motivated by the desire to shorten production time and increase production of safe vesicle dispersions by not using organic solvents or surfactant as disclosed by Tsuchida et al.

Declaration

The Declaration under 37 CFR 1.132 filed March 11, 2008 is insufficient to overcome the rejection of claims 17-21, 24-28 and 32-35 based upon Naru et al. (US Patent Publication US 2004/0033246) in further view of El-Nokaly et al. (US Patent No. 5,688,831) as set forth in the rejection above because:

Applicant shows experimental data that allegedly demonstrates that superior properties of suppressed sphingosine crystal deposition and improved stability are achieved by a composition in accordance with the present invention comprising the claimed vesicle dispersion comprising a branched fatty acid having a melting point of 80°C or less. Applicant compared a composition comprising stearic acid to a composition comprising isostearic acid with the conclusion of unexpected results. Applicant concludes the composition comprising isostearic acid demonstrated superior properties with respect to suppressed sphingosine crystal deposition and improved stability.

Examiner's Response

It would be expected for a composition comprising branched fatty acids compared to straight chain acids to be more stable. It is known that branched fatty acids mimic the properties of the straight chain in many respects; however, they are more stable and more desirable for many applications compared to straight chain fatty acids¹. It is to be noted that the results are not commensurate in scope with the claimed invention. The claimed invention is directed to a branched fatty acid having a melting point of 80°C or less and the experiment is limited to isostearic acid, whereas the instant claims encompass all branched fatty acids.

The Declaration does not overcome the new rejection because the prior art discloses a composition comprising the recited branched fatty acid, as well as the other components recited in the instant claims.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

¹ Roberts et al. (WO 98/07680). This reference is used to disclose that branched fatty acids are more stable than straight chain acids and are more desirable and is not relied upon for the basis of the rejection.

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NANNETTE HOLLOMAN whose telephone number is (571) 270-5231. The examiner can normally be reached on Mon-Fri 800am-500pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/N. H./
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612